BEFORE THE MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

SUBMISSION OF PHILIP MORRIS INCORPORATED, R.J. REYNOLDS TOBACCO COMPANY, BROWN & WILLIAMSON TOBACCO CORPORATION, AND LORILLARD TOBACCO COMPANY

Regarding Proposed Refinements in Sampling and Testing Procedures Set Forth in 105 CMR 660.500 and Certain Other Matters

April 8, 1998

Following are proposals of the above-named manufacturers regarding (1) refinements in the sampling and testing procedures set forth in 105 CMR 660.500 and (2) the multiplier described in 105 CMR 660.102(B)(6), as discussed with representatives of the Massachusetts Department of Public Health ("DPH") on March 26, 1998.

1. **Refinements in the sampling and testing procedures set forth in 105 CMR 660.500.**

Sampling procedure (105 CMR 660.500(A)). Under the sampling procedure specified in § 660.500(A), a manufacturer is required to purchase four packages of each brand style from each of five retailers located in each of five counties in Massachusetts -- a total of 100 packages for every brand style subject to testing. Two packages of each brand style are required to be mailed to DPH from the county in which purchased, leaving 50 packages to be utilized for testing by the manufacturer of the brand style. The 50 packages contain 1000 cigarettes. Testing for each brand style is performed on fewer than 400 cigarettes drawn from the 50 packages.

As the manufacturers explained during our meeting, the prescribed sampling procedure proved to be inefficient and burdensome in 1997, when sampling was limited to

brand families with a national market share of greater than 5 percent (*i.e.*, five brand families representing 87 brand styles). Individual brand styles proved to be unavailable in some retail locations visited, resulting in costly, time-consuming searches that delayed collection and testing. These inefficiencies and burdens will increase substantially in 1998, when the regulations currently call for sampling for brand families with a national market share greater than 1.5 percent (*i.e.*, 13 brand families representing 202 brand styles, according to Maxwell's year-end sales estimates for 1997).[1/]

The prescribed sampling procedure is not necessary, since the cigarettes of each manufacturer that are sold in these 25 retail locations all come into Massachusetts from a common source (the factories in which they are manufactured) via wholesalers. Dr. Rickert of Labstat (while participating in our meeting by phone) reported that, for purposes of Canada's testing program, samples for all of Canada are collected from a single wholesaler in each of two cities. In France, Finland, and the United Kingdom, samples for purposes of ISO testing are collected in the manufacturers' warehouses or factory.

[1/] **Philip Morris** sampled one brand family (Marlboro), representing 20 brand styles, in 1997; it expects to sample five brand families (Marlboro, Basic, Virginia Slims, Merit, and Benson & Hedges) representing 75 brand styles in 1998. **R.J. Reynolds** sampled two brand families (Doral and Winston), representing 35 brand styles in 1997; it expects to sample five brand families (Doral, Winston, Camel, Salem, and the private labels manufactured under the trade name of Forsyth Tobacco Products), representing 77 brand styles, in 1998. **Brown & Williamson** sampled one brand family (GPC), representing 19 brand styles, in 1997; it expects to sample two brand families (GPC and Kool), representing 37 brand styles, in 1998. **Lorillard** sampled one brand family (Newport), representing 13 brand styles, in 1997; it expects to sample no additional brand families in 1998. The number of brand families expected to be sampled in 1998 is based on Maxwell year-end sales estimates for 1997. The Maxwell Consumer Report, Fourth Quarter and Year-End 1997 Sales Estimates for the Cigarette Industry, March 28, 1998.

Proposal. The manufacturers propose that DPH modify its sampling procedure to permit each manufacturer to draw at the point of production (*i.e.*, the factories) the samples of each brand to be tested. For each such brand style, 50 packages would be drawn at random by the manufacturer from the general stock of the brand prior to the removal of such stock to a public warehouse or other distribution facility.[2/] Of the 50 packages drawn, 25 would be utilized for testing and 25 would be mailed to DPH with a certification that the samples had been drawn in the manner and at the time specified.

The manufacturers urge that sampling be permitted at the point of production because, as noted, all cigarettes manufactured by each manufacturer for sale in Massachusetts (and, for that matter, in every other state) come from that common source. In addition, such a sampling procedure would make the most sense from the standpoint of permitting a manufacturer to satisfy jointly the common testing requirements of Massachusetts and Texas. Texas has proposed to require the manufacturers to conduct the same tests on cigarettes sold in Texas that DPH requires the manufacturers to conduct on cigarettes sold in Massachusetts. *The manufacturers seek to avoid the need for "double testing" of cigarettes sold in both Massachusetts and Texas. They seek to be permitted to satisfy the reporting requirements of both states through one set of tests.*

[2/] The manufacturers propose that they be required to draw 50 instead of 100 packages of each brand style because 25 packages, containing a total of 500 cigarettes, would suffice if a manufacturer is permitted to draw up to four cigarettes per package (instead of two) for each of the specified tests.

If you have concerns about permitting sampling at the point of production, the manufacturers ask that you share those concerns with us before making a final decision, so we can explore possible ways of satisfying your concerns.

Alternative proposal. If the manufacturers are ultimately unable to satisfy your concerns about sampling at the point of production, then they propose, alternatively, that each manufacturer be permitted to draw from the stocks of one or more wholesalers within the Commonwealth the samples of each brand style to be tested. For each brand style subject to testing, five cartons (each containing 10 packages) would be drawn at random by the manufacturer from the general stock of the brand style at the wholesaler's warehouse. Of the 50 packages drawn, 25 would be utilized for testing and 25 would be provided to DPH. The manufacturers propose that a representative of DPH be present at the warehouse when the samples are drawn to monitor the sampling and to take delivery of the DPH samples. In addition, the manufacturers propose that DPH select the wholesaler(s) or distributor(s) from which the samples are to be drawn.

Assuming that the final rules adopted by the Texas Department of Health require the manufacturers to conduct the same tests as those required by DPH, and prescribe a reporting deadline sufficient to permit compliance,[1/] the manufacturers would utilize the samples drawn from a wholesaler's warehouse under this procedure to satisfy the testing requirements of Massachusetts and Texas on a joint basis without double testing for cigarettes sold in both states. *To this end, the manufacturers respectfully request that you develop an arrangement*

1/ The manufacturers have asked the Texas Department of Health to permit them to file their first annual reports under the Texas rules on December 1, 1998, the date on which the next annual reports under the Massachusetts rules are due.

with the Texas Health Department that will permit such joint testing. If the procedure for sampling at the point of production is not accepted, the manufacturers would still prefer to draw all of the samples for purposes of the two states' testing requirements from one or more wholesalers located in a single state (*i.e.*, either Massachusetts, Texas, or some third location). Another possibility, however, would be to permit half of the samples to be drawn from a wholesaler or distributor in Massachusetts and the other half from a wholesaler or distributor in Texas. The manufacturers will provide a list of wholesalers in Massachusetts and Texas under separate cover.

Total nicotine content (105 CMR § 660.500(B)). Under the test for measuring total nicotine content specified in § 660.500(B), cigarette manufacturers are required to utilize the testing protocol proposed for smokeless tobacco by the Centers for Disease Control. As the manufacturers explained at our March 26 meeting, and as the manufacturers have explained on several other occasions, this test method was not designed for testing the total nicotine content of the tobacco cut filler in cigarettes, and therefore presents a number of scientific concerns.[2]

Proposal. Ultimately, the manufacturers hope that, through the validation process that the manufacturers understand DPH intends to retain Dr. Rickert to oversee, DPH will select a uniform test for measuring total nicotine content that will be suitable for tobacco cut filler in cigarettes and that will avoid the scientific concerns raised by the CDC's proposed

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[2] *See* Letter dated August 18, 1997, from the Manufacturers to the Public Health Council, p. 2; Letter dated December 15, 1997, from Philip Morris Incorporated to Dr. Gregory N. Connolly, pp. 2-3; Letter dated December 12, 1997, from R.J. Reynolds Tobacco Company to Dr. Gregory N. Connolly, p. 2 n.8.

test method. For purposes of tests conducted in 1998, however, the manufacturers propose that they be permitted to utilize, in lieu of the CDC's proposed method, an equivalent method for measuring total nicotine content approved by DPH.

As Dr. Borgerding discussed at our meeting, other tests are available to measure nicotine content that will produce results that closely approximate the results of the proposed CDC test method. Reynolds has compared the results of testing for nicotine content according to its standard nicotine-content test method with the results of testing according to the proposed CDC method. The results of the tests conducted by a single laboratory using the two test methods were more closely matched than were the results of tests conducted by two different laboratories both using the proposed CDC method. *See* Figs. 1-5.

Percent filter tip ventilation (105 CMR § 660.500(C)). The manufacturers intend to use the method for determining percent filter tip ventilation specified in § 660.500(C). Ultimately, as part of the validation process overseen by Dr. Rickert, the manufacturers will urge consideration of the ISO 9512 format for measuring percent filter tip ventilation.

"Smoke pH" measurement (105 CMR § 660.500(D)). You indicated at our meeting that you contemplate replacing the "smoke pH" measurement specified in § 660.500(D) with a puff-by-puff measurement. The manufacturers seek further discussion regarding a test for puff-by-puff measurement of "smoke pH," which they do not believe will provide additional useful information.

Smoke nicotine yield (105 CMR § 660.500(E))

(a) *Number of cigarettes required to be smoked.* DPH's regulations require 100 cigarettes to be smoked under the DPH regimen, or 20 ports of five cigarettes each. This

is the same number of cigarettes per port required to be smoked pursuant to the FTC test method. 105 CMR § 600.500(E). Because the smoking regimen prescribed by the DPH regimen is more "intense" than the smoking regimen prescribed by the Federal Trade Commission, the possibility exists for exceeding the absorption capacity of the Cambridge filter pads, which were designed to be utilized under the less "intense" FTC regimen. The contract laboratory utilized by R.J. Reynolds for purposes of preparing its 1997 report in fact documented filter-pad breakthrough smoking five cigarettes per port under the DPH regimen.

Proposal. The manufacturers propose that they be permitted to smoke 20 ports of three cigarettes each (instead of five) for purposes of the smoke nicotine yield test specified in § 660.500(E). Dr. Rickert reported during our meeting that this is the standard number of cigarettes per port smoked by his laboratory when using the more "intense" smoking regimen.

(b) *Vent-blocking.* DPH's regulations require that 50 percent of the ventilation holes be blocked by placing a strip of mylar adhesive tape, Scotch Brand No. 600 Transparent (Acetate) "or other method approved by the Department." The tape is to be cut so that it covers 50 percent of the circumference and is tightly secured from the end of the filter to the tipping overwrap seam. 105 CMR § 600.500(E)(4).

As the manufacturers explained at our meeting, the vent-blocking condition is extraordinarily labor-intensive and time-consuming, and--because it is a manual procedure--produces results that are inherently irreproducible and imprecise. On the other hand, as Dr. Borgerding explained, the effect of the vent-blocking condition can be simulated by using

a 55-milliliter puff volume instead of the 45-milliliter puff volume prescribed by DPH.[5] (*See generally* Figs. 6-13.) The increased puff volume functions as a surrogate for the vent-blocking condition specified by DPH. Specifically, testing of Kentucky reference cigarettes in two different laboratories using a 55-milliliter puff volume in lieu of vent-blocking produced results that *matched* the results produced by vent-blocking for lower-yield cigarettes, while for full-flavor cigarettes, the results were slightly higher than the results produced by vent-blocking (*see* Figs. 11-12).[6] Both regimens produced the *same* DPH classification of the Kentucky reference cigarettes tested (*see* Fig. 13). Moreover, with respect to the brand styles tested for the 1997 reports, the yields produced by the DPH regimen using a 45 milliliter puff volume with vent-blocking were generally *lower* than the yields produced by a regimen using a 55-milliliter puff volume without vent-blocking (*see* Fig. 9).

Proposal. The manufacturers propose that they be permitted to measure nicotine delivery for purposes of 105 CMR § 600.500(E)(4) using a 55-milliliter puff volume in lieu of vent-blocking. The reason is entirely practical: If the results produced by the specified vent-blocking condition can be produced by an alternative method that is simpler and also avoids the inherent imprecision and irreproducibility of manual vent-blocking, the alternative

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[5] A regimen utilizing a 55-milliliter puff volume of two seconds' duration drawn every 30 seconds is, in fact, the "upper-tier" regimen proposed by the Federal Trade Commission. *See* 62 Fed. Reg. 48,158 (1997).

[6] Information about the Kentucky reference cigarettes is provided in *Research Cigarettes* (University of Kentucky Tobacco and Health Research Institute, 1990), a copy of which is enclosed. Information regarding the porosity of the paper used in such cigarettes is set forth on page 15 of that document.

method should be used. In addition, the alternative method would provide consistency with the proposed FTC method.

If you have concerns about permitting the use of a 55-milliliter puff volume in lieu of vent-blocking, the manufacturers ask that you share those concerns with us before making a final decision, so they can explore possible ways of satisfying your concerns.

Testing threshold (105 CMR § 660.102(A)(2) & (3)). In 1997, the manufacturers were required to test only those cigarette brand families with a national market share of greater than five percent (§ 660.102(A)(2)). In 1998, when the regulations call for testing cigarette brand families with a national market share greater than 1.5 percent (§ 660.102(A)(3)), with a "multiplier" to be applied to brand families with a market share of less than 1.5 percent for purposes of the smoke nicotine test (§ 660.102(A)(4)).

The manufacturers urge DPH to maintain the five percent threshold for testing because (1) there is no indication that extending testing to other brand families will produce any meaningful additional information regarding total nicotine content (§ 660.500(B)), percent filter tip ventilation (§ 660.500(C)), or "smoke pH" (§ 660.500(D)), and (2) as discussed in detail below, a multiplier is available to predict for other brand families the results of the smoke nicotine test (§ 660.500(E)), which is intended to serve as the basis of the DPH classifications.

(a) *Total nicotine content.* According to the data collected by manufacturers in 1997, the amount of nicotine in the cigarette itself (as measured pursuant to § 660.500(B)) provided no consistent indication of how much smoke nicotine the cigarette would yield when tested under either the standard FTC smoking condition or the smoking conditions

specified by DPH. *See* Appendix A hereto. Since these tests indicate that the amount of nicotine in the smoke from a cigarette cannot be predicted from the amount of nicotine in the tobacco in the cigarette, it is difficult to see what additional information would be obtained by requiring the manufacturers to report the nicotine content of cigarettes other than those tested in 1997.

(b) *Percent filter ventilation.* The data collected by manufacturers in 1997 confirmed that the cigarettes with the highest degrees of filter ventilation (as measured pursuant to § 660.500(C)) yielded smaller amounts of nicotine than cigarettes with lesser degrees of ventilation when cigarettes were smoked under either the standard FTC smoking condition or the smoking conditions specified by DPH. *See* Appendix A hereto. Again, it is difficult to see what additional information would be obtained by requiring the manufacturers to report the percent filter tip ventilation of cigarettes in addition to those tested in 1997.

(c) *"Smoke pH."* Substantial differences were not observed in "smoke pH" levels among the cigarette brand styles that were tested by any single method by any one company in 1997; as such, no correlation between "smoke pH" and smoke nicotine yields was observed for the brand styles tested. *See* Appendix A hereto. Since these results indicate that the amount of "smoke pH" is not correlated with nicotine yield, it is difficult to see what additional information would be obtained by requiring the manufacturers to report the "smoke pH" of cigarettes other than those tested in 1997.

Proposal. The manufacturers propose that they continue to be required to test only cigarette brand families with a market share of greater than five percent, and that they be

permitted to apply a multiplier for purposes of the smoke nicotine test to brand families with a national market share of less than five percent.

2. Development and use of the multiplier described in 105 CMR 660.102(B)(6).

The regulations specify that DPH will establish in consultation with the manufacturers for use in connection with the 1998 reports a multiplier for the purpose of providing the "nicotine delivery" information required by 105 CMR § 660.102(B)(5) for cigarettes with a national market share of less than 1.5 percent.

As Dr. Borgerding discussed, the manufacturers have derived a multiplier from the tests conducted in 1997 that predicts the results of those tests reasonably well. Separate experiments conducted in two laboratories suggest that the relationship between DPH smoke nicotine yields and FTC smoke yields (as found in the most recent FTC report) can be expressed as a quadratic function (*see* Fig. 24). Application of this function to FTC reported nicotine yields for various Kennicky reference cigarettes (which represent a wide variety of smoke yields) demonstrates good agreement between predicted DPH smoke nicotine yields and measured DPH smoke nicotine yields (*see* Figs. 25-26).[7/]

Proposal. The manufacturers propose to use this multiplier for purposes of the 1998 reports. *In addition, the manufacturers respectfully request that they continue to be required*

[7/] The manufacturers also have developed a multiplier predicting the results of testing under a 55/30/2 puffing regimen. *See* Figs. 14-23. At our meeting on March 25 we provided a copy of a report describing the experiment that produced this multiplier. Philipp, C., St. Charles, K., Norman, V., Whidby, J., Garman, J., Lewis, L., Borgerding, M., *An Experiment to Determine the General Relationship Between Cigarette Smoke Yields Using an Alternative Puffing Regimen (55/30/2) and the Standard FTC Method*, compiled by Borgerding, M., Bodnar, J., Willard, B., R.J. Reynolds Tobacco Company, Winston-Salem, N.C. (June 23, 1997). The FTC's proposal would permit the manufacturers to apply this multiplier to all brand styles. *See* 62 Fed. Reg. 48,158 (1997).

to test only brand families with a national market share of greater than five percent, and that they be permitted to utilize the multiplier for all brand families with a national market share of less than five percent. Permitting the use of the multiplier for all such brand families is warranted in view of the enormous testing burden that would be imposed on the manufacturers if the testing threshold is lowered to include brand families with a national market share of greater than 1.5 percent, especially if DPH does not permit the manufacturers to utilize a 55-milliliter puff volume in lieu of vent-blocking.[8/]

As noted, the testing required in 1997 was limited to brand families with a national market share of greater than five percent -- a total of five brand families, representing a total of 87 brand styles. These brand families accounted for 57.9 percent of the cigarettes sold in the United States in 1997.[9/] If the threshold is lowered to include brand families with a national market share of greater than 1.5 percent, the manufacturers would be required to test a total of 13 brand families, representing a total of 202 brand styles. Lowering the threshold from five percent to 1.5 percent would thus require the manufacturers to test more than twice as many brand styles as were tested in 1997. Such an additional testing burden is unnecessary given the availability of a multiplier that can predict the results of actual testing according to the DPH testing regimen and provide the same classifications.

If you have concerns about permitting the use of the proposed multiplier, or about maintaining the testing threshold at brand families with a national market share of greater

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[8/] The manufacturers propose to rely on Maxwell year-end data for 1997. First quarter 1998 data will not be available until mid-summer, after testing is likely to have begun.

[9/] The Maxwell Consumer Report, Fourth Quarter and Year-End 1997 Sales Estimates for the Cigarette Industry, March 28, 1998, Table 4.

than five percent, the manufacturers ask that you share those concerns with us before making a final decision, so they can explore possible ways of satisfying your concerns.